

REMARKS

Overview

In the Office Action under reply, pending claims 38, 40, and 91 were examined, claims 1-37, 39, 41-90, and 92 having been canceled previously. Applicants acknowledge with appreciation the Examiner's withdrawal of the rejection under 35 U.S.C. §102 set forth in the previous Office Action. The pending claims have been rejected under 35 U.S.C. §112, 1st paragraph, for: (1) failing to comply with the enablement requirement; and (2) failing to comply with the written description requirement. The rejections are overcome in part by the amendments made herein, and are otherwise traversed for at least the reasons set forth below.

Claim amendments

With the amendments made herein, claims 38 and 91 has been amended to clarify the claim language. The use of the symbol “~” has been removed, and the claims have been amended to replace the original formula with new formulae specifically showing the orientation of the groups linking Sp to the polymer backbone. This amendment is supported by the original claim language. In addition, claims 93-107 have been added. These claims are supported by the original specification as follows:

Claim	Examples of Supporting Disclosure
93-98, 101-106	Paragraph [0067], original claim 38
99, 107	Paragraph [00112]
100	Paragraph [00113]

Accordingly, no new matter is added.

First rejection under 35 U.S.C. §112, 1st paragraph

Claims 38, 40, and 91 stand rejected under 35 U.S.C. §112, 1st paragraph, as “failing to comply with the enablement requirement” (Action at page 2). The Office Action states that “the specification does not teach the preparation of the copolymers where ‘L¹ is selected from ~O-(CO)-O-, ~(CO)-NH-, ~O-(CO)-NH-, ~S-S-, ~S-(CO)-, and ~(CO)-S-, wherein ~ represents the bond through which L¹ attaches to the polymer backbone” (Action at page 3). This rejection is traversed.

Since the claimed group ~O-(CO)- is not included in the rejection, applicants acknowledge with appreciation the Examiner's recognition that the specification meets the enablement requirement for that group.

Applicants telephoned the Examiner on July 24, 2007, requesting clarification of the rejection. The Examiner stated that applicants must show that each species (i.e., each possible choice for L¹) is enabled by the specification.

According to MPEP §2164.01, in fact, "[t]he standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied." In the pending claims, the linking group connecting Sp with the polymer backbone is selected from -O-(CO)-, -O-(CO)-O-, -(CO)-NH-, and -O-(CO)-NH-. Thus, the relevant question is whether undue experimentation would be required for the skilled artisan to prepare the claimed polymers having any one of these linking groups. As it is clear from the discussion below, undue experimentation would not be required.

MPEP (§2164.01(a)) cites *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), and mentions eight factors that should be considered when determining whether the specification satisfies the enablement requirement and "whether any necessary experimentation is 'undue.'" These factors are: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. It is important to note that the Action does not discuss any of these factors *whatsoever*, but simply states without evidence or reasoning that the claims do not meet the enablement requirement. MPEP §2164.04 states that "[i]n order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." The Office Action provides no basis to question the enablement of the current specification, other than a vague reference to a lack of "adequate description" (Action at pages 2-3). For at least this reason the rejection should be withdrawn.

Furthermore, an analysis of the factors mentioned in *In re Wands* confirm that undue experimentation would not be required. The most pertinent of the factors to be considered for enablement of the instant claims are (C) and (D) - the state of the prior art and the level of one of ordinary skill.¹ As is the case for many inventions pertaining to materials science, synthetic organic chemistry is a component of the claimed invention insofar as the inventive material must be synthesized in order for the skilled artisan to practice the invention. So highly advanced is the state of synthetic organic chemistry, however, that the method for preparing the inventive material is only incidentally associated with the invention. Indeed, the specification describes materials and uses of such materials that are novel. Upon reading the disclosure, the skilled artisan, having a vast array of known synthetic organic chemistry principles at his/her disposal, is provided with all of the necessary components in order to make and use the claimed invention. The specification provides example synthetic procedures (see discussion below), but the crux of the invention are the material and uses themselves, not the methods to make the materials.

Granted, *some* experimentation may be require to make and use the claimed invention, but MPEP §2164.06 states that " 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Because the experimentation that may be required involves synthetic chemistry, and because synthetic organic chemistry is such a highly developed art, *undue* experimentation would not be required to make and use the claimed invention.

In summary of factors (C) and (D), synthetic procedures useful for preparing compounds encompassed by the pending claims are widely available to the skilled artisan. Once the claimed compounds are envisioned (i.e., upon reading the instant claims), the skilled artisan would be capable of preparing such compounds using well-established methods of synthetic organic chemistry.

With reference to factors (F) and (G) listed above, the instant specification provides sufficient guidance and examples to enable the skilled artisan to make and use the claimed invention. According to MPEP §2164.02, "For a claimed genus, representative examples

¹ The skilled artisan is, for example, an industrial chemist having at least a bachelors degree in chemistry.

together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." Such reasoning is not provided in the Action, presumably because the representative examples in the specification are, indeed, sufficient to enable the claims.

The specification contains, for example, specific disclosure pertaining to acrylate-terminated poly(alkylene oxide)s and their use in preparing various polymers and copolymers. Acrylate-terminated poly(alkylene oxide) contains the linking group $-(CO)-O-$, and is a *representative example* that may be used to guide the preparation of the claimed compounds. The skilled artisan would find sufficient guidance for the preparation of the claimed polymers based on the disclosure and the knowledge commonly available in the art. For example, the disclosure of U.S. Patent No. 7,037,992 to Wilson, Jr., et al., filed March 18, 2003 ("Wilson") shows that the groups of the instant claims (i.e., carboxylate ester, carbonate, amide, and urethane) have similar reactivities. Wilson is attached as Exhibit A; see col. 13, line 53 to col. 14, line 27.

A large number of textbooks and/or journal articles pertaining to synthetic organic chemistry could be used to confirm, for example, that a poly(alkylene oxide) terminated with an alcohol group could be used as a starting material to prepare monomers suitable for use in the preparation of the claimed compounds. For example, a terminal alcohol group can be converted to an ester group or carbonate group using oxidation reactions and/or reactions with an activating agent such as phosgene. A terminal alcohol group can be converted to an amide or urethane group by reaction, for example, with a nitrile or isocyanate. See, for example, sections 10-21, 16-6, 16-7, 16-8, and 16-56 from Smith, M.B., and March, J. March's Advanced Organic Chemistry, 5th ed., Wiley (New York, N.Y., 2001), attached hereto as Exhibit B. Hydroxyl-terminated poly(alkylene oxide)s are commercially available, and methods for their preparation are known in the art.

With reference to factor (A) listed above, it is noted that the breadth of the claims is limited to only four possibilities for the linking group. In the art of synthetic chemistry, where a single reaction may be applicable to thousands of different chemical starting materials having a

wide variety of functional groups, the scope of the pending claims is relatively narrow.

Furthermore, as discussed above, the four linking groups of the claims have similar reactivities, indicating that the breadth of the claims is not too large.

In summary, the Office Action provides no explanation or evidence to support a rejection of the claims for lack of enablement. Furthermore, analysis of the relevant factors that are used to determine the validity of such a rejection clearly support applicant's position that the claims are fully enabled by the specification. In light of all of the above factors, applicants respectfully request withdrawal of the rejection.

Second rejection under 35 U.S.C. §112, 1st paragraph

Claims 38, 40, and 91 stand rejected under 35 U.S.C. §112, 1st paragraph, as “failing to comply with the written description requirement” (Action at page 3). The Office Action states that “[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation ‘~O-(CO)-O-, ~(CO)-NH-, ~O-(CO)-NH-, ~S-S-, ~S-(CO)-, and ~(CO)-S-, wherein ~ represents the bond through which L¹ attaches to the polymer backbone’ was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention” (Action at page 3). This rejection is traversed.

Since the claimed group ~O-(CO)- is not included in the rejection, applicants acknowledge with appreciation the Examiner's recognition that the specification meets the written description requirement for that group.

Claims 38 and 91 have been amended to clarify the claim language. Specifically, the amendment removes the symbol “~” from the claims. Furthermore, instead of using the symbol L¹ to represent the groups linking Sp with the polymer backbone, such groups have been explicitly drawn in the claimed formulae.

It must first be noted that MPEP §2163.04(I) states

[i]n rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion.... These findings should: (A) Identify the claim limitation at issue; and (B) Establish a prima facie case by providing reasons why a person skilled in the art at the time the application was

filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed."

The claim limitation at issue is the identity of L¹. The Action provides no basis to support a rejection for lack of written description. The statement made on page 3 of the Action (i.e., that the subject matter is "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention") merely restates the dispositive question at issue, and does not establish a *prima facie* case supporting the rejection. For at least this reason the rejection should be withdrawn.


Furthermore, an analysis of the specification clearly shows that sufficient written description *is* present to support the claims. According to MPEP §2163(I), "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116." As discussed previously, synthetic organic chemistry is a highly advanced art, and the knowledge commonly available (in the form of textbooks, journal articles, patent documents, etc.) is vast. The skilled artisan would be capable of devising synthetic pathways suitable for preparing the claimed compounds based on the specification and the knowledge generally available in the art. Because a wide variety of useful preparatory methods are generally accessible in the art, the skilled artisan would also conclude that applicants had possession of the claimed invention. In other words, since the skilled artisan could recognize synthetic pathways suitable to prepare the claimed compounds, it follows that the inventors of the present application are also able to recognize such pathways. This was true at the time of filing of the instant application, and remains true today.

In summary, the Action does not meet the burden required to support a rejection for lack of written description. Furthermore, it is clear from the specification that applicants had possession of the claimed invention at the time the application was made. Accordingly, the specification provides sufficient written description for the pending claims, and applicants respectfully request withdrawal of the rejection.

CONCLUSION

Applicants submit that the claims of the application are in condition for allowance. Applicants respectfully request withdrawal of the rejections, and prompt issuance of a notice of allowance. If the Examiner has any questions concerning this communication, or would like to discuss the application, the art, or other pertinent matters, a telephone call to the undersigned would be welcomed.

Respectfully submitted,

By: 
Isaac M. Rutenberg
Registration No. 57,419
c/o MINTZ LEVIN
1400 Page Mill Road
Palo Alto, California 94304-1124
(650) 251-7700 Telephone
650) 251-7739 Facsimile
Customer No. 23980